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Ms. Lisa Ni
Product Manager
Tianshi Health Products, Inc.
917-134th Street SW
Suite #A-8
Everett, Washington 98204

Dear Ms. Ni:

This is in response to your letter to the Food and Drug Administration (FDA) dated October 25, 2004. Your letter was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Tianshi Health Products, Inc. is marketing the following products, described as "Tiens Classic Soups," and further named **A Dietary Supplement Containing (Chicken Noodle)**, **A Dietary Supplement Containing (Vegetable Noodle)**, and **A Dietary Supplement Containing (Tomato)**, as dietary supplements.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). The products described above, despite the use of the words "dietary supplement" in their statements of identity are identity labeled as "soup." The use of the term "soup" to describe these products, as well as the use of names commonly associated with soups (such as Chicken Noodle, Vegetable Noodle, and Tomato) evidence that these products are represented for use as "soup," a conventional food. Therefore, in that they are represented for use as conventional food, are not dietary supplements within the meaning of 21 U.S.C. 321(ff) and claims made for them are not subject to 21 U.S.C. 343(r)(6).

Instead, these products appear to be conventional foods that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, they must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the products in their labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food.

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A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market these products as conventional foods and you have any questions about the status of their ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J. Moore
Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



TIANSHI HEALTH PRODUCTS, INC.

October 25, 2004

NOV 04 2004

Dr. Elizabeth Yetley
Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, D.C. 20204

RE: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as a notification of the nutritional support label statements being made by Tianshi Health Products, Inc., located at 917 – 134th Street, S.W., Suite A-8, Everett, Washington, 98204 in connection with the marketing of its line of dietary supplements. A list of the products and their respective nutritional support statements are listed in the attached Exhibit "A".

Tianshi Health Products, Inc. certifies that the information contained in this notice is complete and accurate, and that the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact the undersigned.

Sincerely,


Lisa Ni
Product Manager
Tianshi Health Products, Inc.

917 – 134TH STREET SW, SUITE #A-8 • EVERETT, WA • 98204
PHONE: (425) 741-2289 • FAX: (425) 741-8728

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EXHIBIT A

1. Product: Tiens Classic Soups

A Dietary Supplement Containing (Chicken Noodle):

Enriched Pasta (Durum Flour, Egg Yolks, Niacin, Ferrous Sulfate, Thiamine Mononitrate, Riboflavin, Folic Acid), Maltodextrin, Salt, Cordyceps Powder, Hydrolyzed Soy and Corn Protein, Lactose, Enriched Wheat Flour (Benzoyl Peroxide, Niacin, Reduced Iron, Thiamine Mononitrate, Riboflavin, Chlorine, Folic Acid), Canola Oil, Freeze Dried and/or Dehydrated Chicken, Corn Starch, Dehydrated Carrots, Chicken Fat, Disodium Inosinate and Guanylate, Silicon Dioxide (Anticaking Agent), Autolyzed Yeast Extract, Green Tea Powder, Turmeric, Spices, Seasoning (Autolyzed Yeast Extract, Natural Flavor, Turkey Broth Powder, Maltodextrin, Corn Oil, Sodium Carbonate, Cooked Powdered Turkey, Salt, Soy Sauce [Soybeans, Wheat, Salt]), Dextrose, Sugar, Garlic Powder, Parsley, Celery Seeds, Whey Solids, Egg Yolk Solids, Milk Powder, and Onion Extract.

A Dietary Supplement Containing (Vegetable Noodle):

Enriched Pasta (Durum Flour, Egg Yolks, Niacin, Ferrous Sulfate, Thiamine Mononitrate, Riboflavin, Folic Acid), Dehydrated and/or Freeze Dried Vegetables (Carrots, Onions, Celery, Broccoli, Red Peppers, Green Peppers, Asparagus, Leeks), Hydrolyzed Soy and Corn Protein, Salt, Cordyceps Powder, Corn Syrup Solids, Potato Starch, Dehydrated Yellow Peas, Canola Oil, Spices, Disodium Inosinate and Guanylate, Parsley, Green Tea Powder, Turmeric Extract, Paprika Extract, Celery Extract.

A Dietary Supplement Containing (Tomato):

Tomato Powder, Modified Tapioca Starch, Sugar, Salt, Cordyceps Powder, Corn Syrup Solids, Autolyzed Yeast Extract, Canola Oil, Onion Powder, Spices, Dehydrated Beets, Silicon Dioxide (Anticaking Agent), Disodium Inosinate and Guanylate, Paprika Extract, Citric Acid, Green Tea Powder, Hydrogenated Modified Soy Oil.

Statements of Nutritional Support:

- These ingredients can be used as a key component of any fitness, weight loss, or general nutrition regimen that you are using.**

2. Product: Tiens Bloc

A Dietary Supplement Containing:

White Kidney Bean Extract (Phaseolus Vulgaris)
Cactus Extract (Opuntia Ficus Indica)

Other Ingredients: microcrystalline cellulose, magnesium stearate, gelatin, and water.

Statements of Nutritional Support:

- Phaseolus Vulgaris is an all-natural bean extract, that neutralizes the digestive enzyme alpha amylase before it can convert starch into glucose and then fat, allowing carbohydrates to pass through the system with less caloric intake.*
- Opuntia Ficus-indica contains a natural fiber complex derived from cactus leaf, specifically designed to bind to dietary fats found on the top of the stomach and eliminates them naturally through the gastric system.**

3. Product: Tiens NutraCleanse

A Dietary Supplement Containing:

Fructo-oligosaccharides (FOS)
Glucomannan
Senna Leaf 4:1 (Cassia Senna)

Other Ingredients: microcrystalline cellulose, magnesium stearate, gelatin, and water.

Statements of Nutritional Support:

- The importance of fiber is well known for colon health. It helps aid in better digestion and weight control.* This formula contains Glucomannan, a water-soluble dietary fiber that can help reduce the elevation of blood sugar levels that is typical after a meal. FOS improves the balance of friendly bacteria, improving regularity in the colon.**